Section I

SECTION I - BIOCOMPATIBILITY ASSESSMENT

Overview

The materials described in this section that would possibly come in contact with patient skin or the ear canal have been characterized chemically and physically in the published literature and have a long history of safe use. All materials are identical to that used in legally marketed hearing devices with comparable patient exposure.

Acrylonitrile-butadiene-styrene (ABS) resin

ABS (Cycolac™ Grade X37) is used as a structural material for many devices, specifically hearing aids, which are used in applications with long-term skin contact.

The injection-molding resin employed is a high-heat grade typical of those used for consumer products. No mold release is used in manufacturing the components. Many manufacturers have developed extensive experience with this material across a wide range of products, including similar applications. Because this large base of user experience has been accumulated without adverse effects, ABS is generally recognized as safe in applications such as this.

Thermoplastic Elastomer

The three-flange eartip on the TV-TIP is made of medical grade, synthetic, thermoplastic elastomer. It is the same material used in the commercially available Etymotic Research products ER-20 High-Fidelity earplugs for hearing protection and the ER-4 insert earphones. The same eartip is also used in the commercially available AEARO Corporation Ultrafit earplugs for industry.

Table of Materials

Part	Material	Patient Contact	Probability of Contact	History of Use
Eartip	Thermoplastic elastomer	Ear Canal	High	Widely used material in currently marketed hearing devices.
Case	ABS	Skin	Moderate	